



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

AUG 26 1994

#38

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Dear Mr. Wilson:

This is a corrected copy of my previous letter of August 22, 1994, regarding the filing of an application for extension of the patent term of U.S. Patent No. 4,978,655 issued on December 18, 1990. The previous letter inadvertently omitted the filing date of the application. The letter should have stated that the application was filed on August 19, 1994, under 35 USC § 156.

As noted in my previous letter, since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is **NOT** to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A). I await your assistance in confirming that the product identified in the application has been subjected to a regulatory review period within the meaning of 35 USC § 156(g) before its commercial marketing or use. This communication is **NOT** to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A).

Our review of the application to date indicates that the subject matter would be eligible for extension of the patent term under 35 USC § 156.

C. E. Van Horn

Charles E. Van Horn
Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Dominic M. Mezzapelle
Associate General Counsel-Patents
Bristol-Myers Squibb Company
345 Park Avenue
New York, NY 10154